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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,683	04/12/2005	Eigoro Yamanouchi	260088US3PCT	3880

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,683	Applicant(s) YAMANOUCHI, EIGORO	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-12-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim language if the second magnet must provide a through hole through which the viniculum is actually inserted, so that the first and second magnets are always connected (as in Figure 7) or so that the second magnet has a through hole through which the viniculum is capable of being inserted, although not always connected to the first magnet (as in Figure 9). For examination purposes, it is assumed that the magnet is capable of accepting a viniculum.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cope, et al. (US Patent Number 5,690,656) in view of Hayhurst (US Patent Number 5,601,557) and Grier (US Patent Number 5,595,562).**
6. Regarding Claim 1, Cope'656 teaches a magnetic anastomosing device containing two disc-shaped magnets (90a, 90b, Figure 13). Each magnet can contain a radial through hole (98, Figures 11 and 12) or an axial through hole (96, Figures 9 and 10). Cope'656 teaches that the radial or the axial through hole can be used to orient the magnet (100) on a guidewire (column 5, lines 6-9). Cope'656 further teaches that if a guidewire is not used to place the magnet, a drainage catheter can be used to allow for drainage between the two walls of the viscera (column 5, lines 58-65).
7. Regarding Claim 1, Cope'656 does not teach a moving member, nor does he teach the use of a viniculum.
8. Regarding Claims 1-3, Hayhurst'557 teaches looping a suture (viniculum) (140) through a disc (130) with a latch member (center region of 132, between sutures 140) in order to have two suture members (140) available for anchoring the disc (130) (column 10, lines 15-26).
9. Regarding Claim 4, Hayhurst'557 teaches that the suture (140) can be made out of a bioabsorbable material in order to prevent long-term irritation of the surrounding tissues (column 3, lines 15-20).

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10. Regarding Claims 1 and 6, Grier'562 teaches a method of magnetic enteral gastronomy that includes introducing a magnet into a patient's stomach by affixing the magnet to the tip of a moving member and using the tube to push the magnet into place (column 3, lines 55-58). This method of introducing the magnet may be chosen based on the patient's condition (column 2, lines 52-63).

11. Therefore it would have been obvious to one skilled in the art at the time of the invention to teach a magnetic anastomosing device containing two magnets with a through hole for a guide wire for moving the magnet and a through hole for a viniculum used to orient the magnet, as well as a moving member to place the magnet inside of the patient.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cope'656, Hayhurst'557 and Grier'562, as applied to Claim 1, in further view of Reo, et al. (US Patent Application Number 2002/0072758).

13. Cope'656 and Hayhurst'557 teach the limitations of Claim 1, as described above. Cope'656 and Hayhurst'557 do not teach the use of chamfered corners on the magnet.

14. Reo'758 teaches a magnetic anastomosing device in which he states it is known to round the corners of the magnet for atraumatic deployment (paragraph [0040]).

Therefore it would have been obvious to one skilled in the art at the time of the invention to use chamfered corners on a magnet used in an anastomosing device in order to allow for atraumatic deployment of the magnet.

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15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cope'656, Hayhurst'557 and Grier'562, as applied to Claim 1, in further view of Cole, et al. (US Patent Number 6,719,768).

16. Cope'656 and Hayhurst'557 teach the limitations of Claim 1, as described above. Cope'656 and Hayhurst'557 do not teach the use of a marker that indicates the magnetic pole of the material.

17. Cole'768 teaches a magnetic anastomosing device that contains a visual marker on the magnet that indicates the polarity of the magnetic field (column 23, lines 36-48). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a visual marker on a magnet used in an anastomosing device to indicate the polarity of the magnet.

Allowable Subject Matter

18. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 8 is allowed because of the need to use by organ anastomosing device by introducing the first magnet with a guidewire and moving member, and then orient first magnet with a viniculum after removing the guide wire from the through hole in the first magnet.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hendren (US Patent 3,986,493) discloses a method of anastomosing with magnets.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER